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10/823,114	04/13/2004	Joseph A. Matthias	CU60221	3527

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EXAMINER
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LUBIN, VALERIE

ART UNIT	PAPER NUMBER
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4137

MAIL DATE	DELIVERY MODE
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04/30/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/823,114	<b>Applicant(s)</b> MATTHIAS, JOSEPH A.	
	<b>Examiner</b> VALERIE LUBIN	<b>Art Unit</b> 4137	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)                    |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application          |
| Paper No(s)/Mail Date <u>6/24/04</u> .   | 6) <input checked="" type="checkbox"/> Other: <u>EAST search history</u> . |

## **DETAILED ACTION**

### ***Acknowledgements***

1. Claims 1-35 are pending

For reference purposes, the document paper number is 20080424

### ***Claim Rejections - 35 USC § 101***

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-33 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

4. Claims 1, 2, 3 and 19 are directed to methods comprising abstract steps (e.g. conducting, determining, enrolling, performing, providing, segregating, etc.) that do not provide a useful, concrete and tangible result in the art. The methods should include steps that provide a practical application of the claimed abstract concepts.

Claim 6 as a dependent of claim 2, claims 4, 5, 7-18 as dependents of claim 3 and claims 20-33, as dependents of claim 19 are also rejected under the above analysis.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 3-5, and 7-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 3 and 19 are directed to a method comprising the step of “enrolling a plurality of customers sufficiently meeting predetermined qualifying requirements...” It is unclear what Applicant means by “sufficiently” as Applicant does not provide a standard in his specification for measuring the degree intended by “sufficiently” (MPEP 2173.05 (b)). For examining purposes, the limitation shall be interpreted as: enrolling a plurality of customers meeting predetermined qualifying requirements.

Claims 4, 5, 7-18 and 20-33, as dependents of claims 3 and 19, are rejected under the same analysis.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by McAlindon et al., U.S. Patent No. 7,251,609.

10. McAlindon teaches a method of conducting a clinical study among human subjects (Abstract).

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 2-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over McAlindon et al., U.S. Patent No. 7,251,609 in view of Brown et al., U.S. Patent No. 5,879,163.

13. With regards to claim 2, McAlindon teaches a method comprising the step of conducting an online clinical study among consumers (Abstract).

McAlindon does teach determining the efficacy of a drug used in the study (Col. 3, lines 17-20), but he does not disclose evaluating the efficacy of behavioral material. However, Brown does disclose providing customized behavioral material to an individual at a remote terminal (Abstract) and evaluating such material's performance (Fig. 8, element 230). It would therefore have been obvious to one of ordinary skill in the art to combine the teachings of McAlindon and Brown to facilitate the evaluation of the behavioral material's effectiveness during the study.

14. With respect to claim 3, McAlindon discloses:

- a) enrolling a plurality of customers of customers meeting predetermined qualifying requirements (Col. 4, lines 27-42);
- b) performing a computerized initial evaluation of a customer (Col. 4, lines 27-42);
- c) randomly segregating the plurality of customers into a first group which accesses the test substance and a second group which accesses another substance; (d) providing the first group with a test substance and (e) providing the second group with a non-testing substance (Col. 5, lines 46-48). Although McAlindon does not disclose access to the behavioral material in question, Brown provides access to such material via a remote terminal

(Abstract). Therefore, it would have been obvious to combine McAlindon and Brown as the material accessed is a mere substitution of one known element for another (Ex parte Smith, 83 USPQ2d 1509 (Bd. Pat. App. & Int. 2007)).

McAlindon also discloses:

f) providing the first and second groups with a computerized first series of questions and (g) providing the groups with a second series of questions (Col. 10, lines 63-66).

h) analyzing the responses of the groups to the first and second series of questions (Col 10., lines 66, 67; col. 11, lines 1-4).

For limitation (i), McAlindon does recite determining the effects of the drugs/substances used in the study (Col. 3, lines 17-20), but he does not disclose evaluating the efficacy of tailored behavioral material with the non-tailored material. However, Brown does disclose providing customized behavioral material to an individual at a remote terminal (Abstract) and evaluating such material's performance (Fig. 8, element 230).

Claim 19 is rejected under the analysis of claim 3, as Brown discloses providing smoking-cessation related material (Fig 7, 8; col. 7-11). Indeed, Brown's invention, based on responses to questions related to smoking, creates individual profiles and sends customized behavioral material to participants in order to decrease and cease smoking habits.

Claims 13 and 29 are rejected under the analysis of claim 3, as it would have been obvious to one of ordinary skill in the art to continue enrollment until a desired number of participants is reached.

15. Concerning claim 4, McAlindon discloses determining a period of time for initiation and termination of the online clinical study (Col. 15, lines 30-34).

Claim 20 is rejected under the analysis of claim 4

16. Claim 5 is rendered obvious, as McAlindon recites determining a quantity of customers desired for the online clinical study (Col. 13, lines 64-67; col. 14, lines 1-4).

Claim 21 is rejected under the analysis of claim 5.

17. Claim 6 is rejected, as McAlindon discloses participants receiving medication (Col. 3, lines 17-21).

Claim 22 is rejected under the analysis of claim 6, because it would have been obvious to one of ordinary skill to provide medication related to the condition being studied and treated, i.e. smoking in order to obtain desired results, i.e. smoking cessation.

18. For claim 7, McAlindon discloses participants providing clinical information such as an email address (Col. 4, lines 51-53), age and gender (Col. 9, line 34); and Brown recites providing smoking history (Col. 7, lines 29,30). Although McAlindon does not specifically recite "a predetermined length of time as a smoker," it would have been obvious to one of ordinary skill in the art to include whatever information relating to the smoking history of Brown (e.g. years as a smoker) for the purpose of conducting a clinical study.

Claim 23 is rejected under the analysis of claim 7.

19. With respect to claim 8, McAlindon and Brown both disclose assessing program utilization and program satisfaction or performance (McAlindon, col. 11, lines 29-33; Brown, col. 11, lines 28-30, 49-52). Although McAlindon does not disclose smoking abstinence, it would have been obvious to one of ordinary skill in the art to inquire about smoking



abstinence as a sign of the improvement recited by Brown in order to assess smoking cessation behavior.

Claim 24 is rejected under the analysis of claim 8.

20. Claim 9 is rejected, as McAlindon recites collecting initial evaluation and series of questions using a web-based computer interface (Col. 4, lines 27-42). Brown also recites collecting an initial evaluation using a web-based computer interface (Abstract; col. 6, lines 49-50).

Claim 25 is rejected under the analysis of claims 9.

21. Claim 10 is rejected, as McAlindon recites evaluating customers in the study (Col. 3, lines 17-20), and Brown teaches individuals accessing behavioral support material online or remotely (Abstract).

Claim 26 is rejected under the analysis of claim 10.

22. Claim 11 is rendered obvious over the prior art, as McAlindon discloses notifying qualified participants to log in for a first visit (Col. 6, lines 34-37), and Brown recites transferring educational material to individuals' remote terminals (Col. 11., lines 10-14).

Claim 27 is rejected under the analysis of claim 11.

23. Regarding claim 12, Brown discloses providing participants with ongoing educational material (Col. 11, lines 55-58). It would therefore have been obvious to one of ordinary skill in the art to employ whatever means possible and available to provide such material (e.g. emails, mail, etc) ( Ex parte Smith, 83 USPQ2d 1509 (Bd. Pat. App. & Int. 2007)).

Claim 28 is rejected under the analysis of claim 12.

24. With respect to claim 14, McAlindon discloses health related websites as gateways to the trial's website (Col. 4, lines 1-11)), and individuals enrolling through the trial's website (Col. 4, lines 24-25). McAlindon does not specifically recite that the enrolling website is that of a medical provider, however, the claim is rendered obvious, as a website can be any kind of website for the purpose of enrolling in clinical studies (e.g. hospitals, universities, healthcare providers, etc).

Claim 30 is rejected under the analysis of claim 14.

25. Claim 15 and 31 are rejected as obvious over McAlindon, as he discloses assessing compliance with medication use (Col. 23, lines 31-33; col. 24, lines 16-27).

26. Claims 16 and 32 are rejected, as McAlindon recites providing compensation to study participants (Co. 24, lines 45-47).

27. With regards to claim 17, McAlindon discloses evaluating personal opinions as indicated in the assessment form in Figure 9.

28. With respect to claims 18 and 33, although McAlindon accounts for smoking behavior after treatment begins in the study (Figure 9); he does not specifically recite using mathematical analysis based on smoking cessation rates. However, mathematical analyses of smoking cessation rates are old and well known in the art.

29. For claim 34, Examiner already showed that McAlindon discloses a website (Col. 4, lines 24-26). Both, McAlindon and Brown disclose a computer and network (Abstract). Brown recites an automated education system, and an analyzing mechanism (Abstract).

Claim 35 is rejected under the analysis of claim 34, as Brown discloses smoking cessation material (Col 7-11).

### ***Conclusion***

30. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hess, U.S. Patent No. 6,233,488 discloses using meta-analysis to evaluate smoking cessation rates.

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE LUBIN whose telephone number is (571)270-5295. The examiner can normally be reached on Monday-Friday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Calvin Hewitt can be reached on 571-272-6709. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VL

/Calvin L Hewitt II/

Supervisory Patent Examiner, Art Unit 4137